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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,324

12/20/2004

Zicai Liang

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KRATZ, QUINTOS & HANSON, LLP
1420 K Street, N.W.
4th Floor
WASHINGTON, DC 20005

EXAMINER

SHIN, DANA H

ART UNIT

PAPER NUMBER

1635

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,324	Applicant(s) LIANG ET AL.	
	Examiner DANA SHIN	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10 and 12-20 is/are pending in the application.
- 4a) Of the above claim(s) 13-15, 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 12, 16, 17 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12-20-04, 1-25-05, 11-27-06</u> | 6) <input checked="" type="checkbox"/> Other: <u>Notice to Comply</u> |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of claims 1-12, 16-17, and 20 in the reply filed on May 26, 2010 is acknowledged. The traversal is on the ground(s) that Groups I and V share a corresponding special technical feature because all the features of claim 1 (e.g., mutated promoters), for example, are not taught by the prior art of Beach et al. This is not found persuasive because the claimed DNA library in the instant case is still found to have no special technical features that defines a contribution over prior art. See the prior art rejections below.

The requirement is still deemed proper and is therefore made FINAL.

Status of Claims

Claims 1-8, 10, and 12-20 are pending in the instant case. Claims 13-15 and 18-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Accordingly, claims 1-8, 10, 12, 16-17, and 20 are under examination on the merits in the instant case.

Information Disclosure Statement

The information disclosure statement (IDS) filed on November 27, 2006 has been placed in the application file, but the information referred to therein has not been considered as to the merits. The IDS identifies the applicant as "Susumo MUTO et al." and the filing date as September 3, 2004. However, there is no co-inventor/applicant having such name, nor does the

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filing date correspond to the filing date of the instant application or the PCT application. Further, no single reference disclosed in the IDS appears relevant to the claimed subject matter in the instant case. Clarification is required. In addition, applicant is required to provide relevance of the references to the claimed subject matter for examiner's consideration of the references.

Specification

The disclosure is objected to for containing sequence rule non-compliant subject matter. See pages 5-8 and Figures 1A, 2A, 3A, 3B, 4A, and 4B, which contain nucleotide sequences that are at least 10 nucleotides in length, wherein the sequences are not accompanied by appropriate SEQ ID NOs. See also the attached Notice to Comply.

Appropriate correction is required.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35

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U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/390,108, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. It is found that the disclosure of 60/390,108 does not provide adequate support for the claimed DNA library having mutated promoters. Note that applicant has explicitly argued that the special technical feature of the claims resides in the fact that the DNA library contains “mutated” promoters. See page 7 of remarks filed on May 26, 2010. Hence, the benefit of an earlier filing date for claims 1-8, 10, 12, 16-17, and 2 is granted only insofar as the filing date of PCT/SE2003/001077, which is June 23, 2003.

If applicant believes that the claimed subject matter is adequately described in 60/390,108 in the manner provided by the first paragraph of 35 U.S.C. 112, applicant is advised to point out the particulars in response to this Office action.

Claim Objections

Claims 1 and 3 are objected to because of the following informalities:

- 1) the word “where” in claim 1, line 3 should be “wherein”.
- 2) the phrase “each dsRNA comprise” in claim 1, line 3 should be “each dsRNA comprises”.
- 3) the word “dsRAN” in claim 3, line 1 should be “dsRNA”.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 10, 12, 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "each of said promoters" in line 5. There is insufficient antecedent basis for this limitation in the claim because there is no recitation of "promoters" preceding the limitation.

Claim 3 recites the limitation "said dsRAN-" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 3 also recites "randomized in between 4 and all positions." It is unclear what is exactly meant by the numerical value "4" recited in line 2. Further, note that the dsRNA is claimed to be contiguously encoded by "both strands". See claim 1. Hence, even if the numerical value "4" is meant to indicate a nucleotide position of a dsRNA-encoding sequence, the structure of claim 3 is ambiguous because one cannot ascertain which of the nucleotide position 4 within a single "sequence" of the "both strands" is randomized, thereby rendering the claim indefinite.

Regarding claim 10, the phrase "the source RNA (or mRNA)" renders the claim indefinite because it is unclear whether the limitation within the pair of parentheses is part of the claimed invention. See MPEP § 2173.05(d).

Claims 2-8, 10, 12, and 16-17 depend from claim 1. Claim 1 recites “each dsRNA comprise a stretch” in line 3. However, the claim does not particularly point out or distinctly claim what is meant by the term “stretch” or what constitutes the “stretch”. That is, the identity or structure of the claimed “stretch” remains unknown and thus one cannot ascertain the metes and bounds regarding the phrase “each dsRNA comprise a stretch”, thereby rendering claims 1-8, 10, 12, and 16-17 indefinite.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 10, 12, and 16-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a DNA library or variants thereof that produces a "dsRNA-encoding sequence of 10-30 base pairs".

With regard to the practical utility/functionality of the claimed dsRNA, the instant specification teaches that “It is acknowledged that most frequently used double stranded RNA is siRNA of 19-21 base pairs in length”. See page 11. In addition, the specification teaches that the

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claimed library is intended to be used for “knockdown gene expression” for “drug target screening”. See page 12. As such, the claimed dsRNA must have a function that can silence or knock down target expression in cells via RNA interference. However, as explicitly disclosed in the instant specification, a dsRNA that is shorter than about 19 base pairs in length was not known to mediate RNA interference in cells. Further, the instant specification is silent about whether a dsRNA of 10 base pairs has practical utility such that it is capable of silencing target expression by RNA interference. As such, there is no structure/function correlation for the claimed genus of 10-30 base pairs and the requisite inherent function of target silencing. Note that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species. A “representative number of species” means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure “indicates that the patentee has invented species sufficient to constitute the gen[us].” See *Enzo Biochem*, 323 F.3d at 966, 63 USPQ2d at 1615; *Noelle v. Lederman*, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004)(“[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated.”). See also MPEP §2163.

In light of the above, the instant specification does not clearly allow persons of ordinary skill in the art to recognize that the inventors invented the genus claimed in the instant case.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, 10, 12, 16-17, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Li et al. (US 2004/0146858 A1).

Li et al. teach a plasmid vector-based DNA library comprising randomized DNA sequences of 17-23 base pairs encoding randomized dsRNA/siRNA sequences, flanked by two mutated/modified pol III promoters facing each other, wherein the mutated/modified promoters contain complementary termination sequences (e.g., at least four consecutive A's complementary to at least four T's) wherein the pol III promoters include H1 RNA promoters and U6 snRNA promoters. They teach that dsRNA/siRNA contains a 3' overhang of two or more nucleotides when the dsDNA sequence (the 3' overhang sequence being preferably two T's in the dsDNA sequence) is transcribed from the pol III promoters. They teach that the randomized sequences can be known target sequences such that the randomized siRNA sequences produced can be used to inhibit expression of a variety of cellular origin. See paragraphs 0005-0006, 0045, 0079, 0100-0106, 0168-0172, 0187-0189, 0214-0232; claims 1-12. Accordingly, all claim limitations are taught by Li et al.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Friday, 7am-3:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low (Acting SPE) can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Primary Examiner
Art Unit 1635

/Dana Shin/
Primary Examiner, Art Unit 1635